DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 99-NWJ-39

September 29, 1999

Hueng Choe
President
Tokyo House, Inc.
7550 North Crescent Boulevard, Unit C
Pennsauken, NJ 08109

Dear Mr. Choe:

During an inspection on June 8, 1999, at your firm located at the above address, our Investigator documented violations of Section 123 of Title 21, Code of Federal Regulations. The violations of the Fish and Fishery Product (HACCP) regulations cause your products --California sushi rolls, tuna sushi rolls, salmon sushi rolls, and nigiri-sushi (using tuna, octopus, shrimp, eel, surimi, salmon, snapper, smelt roe, and clams) -- to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), whereby your products were prepared, packed or held under insanitary conditions whereby they may have rendered injurious to health.

The inspectional observations of concern were:

- You are required to implement the monitoring procedures listed in your HACCP plans in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of checking the temperature of the cooler and documenting the results on a temperature log at the critical control point of thawing to control the hazards of histamine formation and pathogen growth.

- You are required to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.8(a). However, your firm did not perform calibration of process-monitoring instruments; specifically, thermometers used to report the temperatures in your coolers and freezers.

- You are required to have sanitation control records that adequately document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your sanitation control records do not document the monitoring for the condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand-washing, hand-sanitizing and toilet facilities; protection of food and packaging material and food contact surfaces from adulterants; proper labeling and storage and use of toxic compounds; control of employees with adverse health conditions; and exclusion of pests.

- In addition to the violations noted above, our Investigator documented that the temperature of cooked rice was above 70° F for more than three hours during the inspection. The cooked rice was held in covered pans inside a cooler measuring 68° F before it was eventually used in preparing sushi products *[21 CFR 123.6(a)].*

The first two observations were previously reported to you in a letter from this office, dated March 29, 1999, referencing an inspection by the New Jersey Department of Health, performed under contract with the FDA. Correspondence from you, dated May 27, 1999, indicated that all deficiencies referenced in that letter were corrected or were in process.

The above items are not intended to be an all-inclusive list of violations. As a manufacturer of cooked and uncooked ready-to-eat human food, you are responsible for assuring that your overall operation and the food products themselves are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. *Also, please provide clarification on your vinegar acidification process involving your rice, as your HACCP plan does not indicate whether acidification occurs prior to cooking or after cooking and state whether time/temperature or pH is used as the critical control point.* If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

Edward H. Wilkens, for
Douglas I. Ellsworth
District Director